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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/762,223

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Antony Walter Anson

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Intellectual Property Dept.
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EXAMINER

WOO, JULIAN W

ART UNIT

PAPER NUMBER

3773

MAIL DATE

DELIVERY MODE

01/10/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/762,223

Applicant(s)

ANSON ET AL.

Examiner

Julian W. Woo

Art Unit

3773

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 51, 53, 55-64, 67 and 68 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 62 is/are allowed.
- 6) ☒ Claim(s) 51, 53, 55-61, 63, 64, 67 and 68 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 11/29/07.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application
- ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 29, 2007 has been entered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 64, 67, 68, 71, and 72 are rejected under 35 U.S.C. 102(b) as being anticipated by Harrild (1,036,229). Harrild discloses, at least in figures 1 and 2, a fixator comprising one or more elongated members (1), each elongated member extending between first and second parts, where the first and second parts (the opposing end portions) are sharpened, where each elongated member has an open configuration (see fig. 1) with first and second parts that are distant and aligned along a common axis, first and second parts adjacently situated with their lengths in abutment (at central portions) and substantially coaxial, and where the fixator has a substantially uniform cross-sectional area as it extends from its first parts to its second parts; and a retaining

configuration (see fig. 2), where the first and second parts are closely spaced, where the each elongated member is biased or bent towards the retaining configuration (after being driven into a medium), where the first and second parts define terminal ends, and where the fixator has a substantially uniform cross-sectional area between the non-sharpened portions of the first and second parts when the elongated members are in the open configuration. Note: The introductory statement of intended use ("for retaining a graft on an artery") has been carefully considered but deemed not to impose any structural limitations on the claims patentably distinguishable over Harrild's device, which is capable of being used as claimed if one desires to do so.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. Claims 51, 53, 55 -61, 63, 70, and 73-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harrild (1,036,229) in view of Berg et al. (6,994,713). Harrild

discloses the invention substantially as claimed. Harrild discloses a fixator including, inter alia, a plurality of sharpened, integral, first and second parts (opposing end portions of elements 1) and a member (central portions of elements 1 and 2) connecting the first and second parts, where the first and second parts are movable into open and retaining configurations, wherein the open configuration, the cross-sectional areas of each of the first and second parts are substantially equal to the cross-sectional area of the member; where the first and second parts form arcuate shapes when in the retaining configuration, where the device is formed from one or more wires, where the wires are linked together by (i.e., integrated with) a wire (2), where the fixator extends through a graft (unlabeled as seen in fig. 2) with first parts contacting the surface of the graft (at driving of the fixator) and the member extending through the graft, and where the first and second parts are adjacently aligned in abutment with each other (at central portions of elements 1 and 2). However, Harrild does not disclose that the member is resilient and the device is formed of a shape memory alloy, where each elongated member is normally biased into the retaining configuration. Berg et al. teach, at least in figures 1,13-15 and 18 and in col. 2, lines 3-55; col. 4, lines 4-65; and col. 7, line 14 to col. 8, line 26; a fixator for retaining a graft on an artery, where the fixator includes a plurality of first parts (14 at one end), at least one second part (14 at another end), a resilient member (16) connecting the first and second parts, where the resilient member biases the first and second parts toward each other into a retaining configuration (e.g., see fig. 18), where the device is formed from a shape memory alloy (e.g., nitinol), and where each elongated member is normally biased into the retaining configuration. It

would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Berg, to modify the device of Harrild, so that that the member is resilient and the device is formed of a shape memory alloy, where each elongated member is normally biased into the retaining configuration. Such a modification would produce a strong device that is biocompatible and corrosion-resistant, and it would improve the retention between parts joined together by biased elongated members. Moreover, it would be obvious to apply a shape memory alloy in the device of Harrild, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

Response to Amendment

6. Applicant's arguments with respect to claims 51, 53, 55-61, 63, 64, 67, 68, and 70-75 have been considered but are moot in view of the new ground(s) of rejection.

Allowable Subject Matter

7. Claim 62 is allowed.

8. The following is a statement of reasons for allowance: None of the prior art of record, alone or in combination, discloses a fixator included in a kit, where the fixator includes, inter alia, a plurality of first parts, at least one second part, and a resilient member connecting the first and second parts; and where the kit includes, inter alia, a device for supporting a catheter having a locating member, a plurality of support

members, and resilient member, and a device for dilating an artery having a locating member, a plurality of dilating members, and a resilient member.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Gilmer (1,150,358) teaches a fixator.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic
Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, reading "Julian W. Woo". The signature is written in a cursive style with a large, stylized 'J' and 'W'.

Julian W. Woo
Primary Examiner

January 7, 2008